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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,840	09/08/2003	Mark W. Kroll	A03P1062US03	1754

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PACESETTER, INC.
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EXAMINER

JOHNSON, SHEVON ELIZABETH

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/657,840		KROLL ET AL.	
	Examiner		Art Unit	
	Shevon E. Johnson		3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 11-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) 9, 10, 16 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/6/2006</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 2. Claims 2, 6 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersson et al. (U.S. Patent No. 5,846,264).**

In regards to claim 6, Andersson et al. discloses a system 4 comprising: a pacing unit for delivering primary pacing pulses to the heart C1; a pulse capture detection unit operative to detect loss of capture of primary pacing pulses 5; and a backup pulse unit for delivering backup pulses to the heart upon detection of a loss of capture of a primary pacing pulse C3; and wherein the capture detection unit is further operative to detect loss of capture of backup pacing pulses 5 (col. 2, lines 35-64, Fig. 1).

In regards to claims 2 and 12, Andersson et al. discloses a system 4 wherein the pacing unit delivers primary pacing pulses at a pulse magnitude less (1.5 volts) than a predetermined maximum pulse magnitude and wherein the backup pulse unit delivers a backup pulse at the maximum pulse magnitude (4.5 volts) (col. 2, lines 35-64).

In regards to claim 11, Andersson et al. discloses a method comprising: delivering primary pacing pulses to the heart; verifying capture of the primary pacing pulses; delivering a backup pulse to the heart upon detection of a loss of capture of a primary pacing pulse; and verifying capture of the backup pacing pulses (col. 1, lines 29-51 and col. 2, lines 35-64).

- 3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (U.S. Patent No. 5,861,008).**

In regards to claim 1, Obel et al. discloses a system comprising: a pacing unit for delivering primary pacing pulses to the heart 8; a pulse capture detection unit operative to detect loss of capture of primary pacing pulses 5 and 14; and a backup pulse unit for delivering backup pulses to the heart upon detection of a loss of capture of a primary pacing pulse 9; and wherein the capture detection unit is further operative to detect loss of capture of backup pacing pulses 5 and 14 (col. 7, lines 1-45, Fig. 4).

4. Claims 11, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. (U.S. Patent No. 6,038,474).

In regards to claims 11 and 12, Zhu et al. discloses a method comprising: delivering primary pacing pulses to the heart 118; verifying capture of the primary pacing pulses 120; delivering a backup pulse to the heart upon detection of a loss of capture of a primary pacing pulse 132; and verifying capture of the backup pacing pulses 134; and wherein the primary pacing pulse and backup pulse are delivered having a predetermined output (col. 7, lines 17-43; Fig. 7).

In regards to claim 13, Zhu et al. discloses a method wherein the controller operative to determine a capture threshold for pacing pulses if a primary pacing pulse is not captured but a backup pulse is captured (col. 7, lines 33-43; Fig. 7).

5. Claims 1-8 and 11-14, are rejected under 35 U.S.C. 102(e) as being anticipated by Bradley et al. (U.S. Patent Pub. No. 20030208241).

In regards to claims 1 and 11, Bradley et al. discloses implantable cardiac stimulation device 10 for implant within a patient, a system comprising a microcontroller 60 that carries out the functions of the pacing unit, pulse capture detection unit, and the backup pulse unit as claimed by applicant. The microcontroller 60 uses a program module that implements the following method of delivering primary pacing pulses to the heart 202; verifying capture of the primary pacing pulses 204; delivering a backup pulse to the heart upon detection of a loss of capture of a primary pacing pulse 210; and verifying capture of the backup pacing pulses 211 (pg. 4, [0051-0052], Fig. 3).

In regards to claims 2, 3, 4 and 12, Bradley et al. discloses a system 10 wherein the pacing unit triggers the delivery of primary pacing pulses at a pulse magnitude less 202 than a predetermined

maximum pulse magnitude and the backup pulse unit delivers a backup pulse at the maximum pulse magnitude a stimulation threshold search unit 60 operative to determine a capture threshold for primary pacing pulses, and wherein the stimulation threshold search unit is activated if a programmable number of consecutive primary pacing pulses do not capture but corresponding backup pulses do capture. (pg. 6, [0050-0052], Fig. 3).

In regards to claims 6-8, Bradley et al. inherently discloses a system when in the controller can perform the task of a capture-based tachycardia detection unit operative to detect an tachycardia based upon loss of capture of backup pacing pulses [0040]; an antitachycardia pacing (ATP) unit operative to deliver antitachycardia pacing therapy to the heart [0040], and wherein the primary pacing unit delivers overdrive pacing therapy while a tachycardia is not detected and to instead activate the ATP unit upon detection [0043] (pgs. 4-5, Fig. 2).

In regards to claim 13, Bradley et al. discloses a method of performing a stimulation threshold search using the stimulation threshold search unit if a primary pacing pulse is not captured but a backup pulse is captured (pg. 6, [0052], Fig. 3).

In regards to claim 14, Bradley et al. discloses a method wherein delivering primary pacing pulses to the heart is performed in accordance with preventive overdrive pacing (pg. 6, [0050-0052], Fig. 3).

6. Claims 1 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Bornzin et al. (U.S. Patent No. 6,456,881).

In regards to claims 1 and 11, Bornzin et al. discloses implantable cardiac stimulation device 10 for implant within a patient, a system comprising a microcontroller 60 that carries out the functions of the pacing unit, pulse capture detection unit, and the backup pulse unit as claimed by applicant. The microcontroller 60 uses a program module that implements the following method of delivering primary pacing pulses to the heart 305; verifying capture of the primary pacing pulses 332; delivering a backup pulse to the heart upon detection of a loss of capture of a primary pacing pulse 350; and verifying capture of the backup pacing pulses 355 (col. 7, lines 41-43; col. 9, lines 8-17; Fig. 3).

7. Claims 1 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Lu (U.S. Patent No. 6,697,673).

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In regards to claims 1 and 11, Lu discloses implantable cardiac stimulation device 10 for implant within a patient, a system comprising a microcontroller 60 that carries out the functions of the pacing unit, pulse capture detection unit, and the backup pulse unit as claimed by applicant. The microcontroller 60 uses a program module that implements the following method of delivering primary pacing pulses to the heart 305; verifying capture of the primary pacing pulses 310; delivering a backup pulse to the heart upon detection of a loss of capture of a primary pacing pulse 352; and verifying capture of the backup pacing pulses 355 (col. 10, lines 23-38; col. 11, lines 28-33; Fig. 3).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradley et al. (U.S. Patent Pub. 20030208241) in view of Olson et al. (U.S. Patent No. 6, 731, 978).

In regards to claims 15 and 18-20, Bradley et al. discloses the stimulation device for performing antitachycardia pacing (ATP) therapy except the method for delivering ATP therapy if both a primary pacing pulse and a backup pulse are not captured. However, Olson et al. teaches a method wherein the controller may apply different set of rules where appropriate. Particularly, apply a rule wherein if certain conditions are not met the controller can inhibit the delivery of antiarrhythmia therapy until a rule is met or the controller deems it necessary in a special situation (col. 2-3 and col. 16, lines 34-48, Figs. 2 and 11). Therefore, it would have been obvious to one of ordinary skill in the art to have incorporated the method as set forth by the controller as taught by Olson et al. for the controller as disclosed by Bradley to provide an antitachycardia therapy to a patient's heart.

Allowable Subject Matter

10. Claims 9, 10, 16 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon E. Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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